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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/933,366	08/20/2001	Sandra M. Sims	3523/2/US	4928

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EXAMINER
DELACROIX MUIRHEI, CYBILLE

ART UNIT	PAPER NUMBER
1614	19

DATE MAILED: 08/01/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/933,366	SIMS, SANDRA M.	
	Examiner	Art Unit	
	Cybille Delacroix-Muirheid	1614	

-- The MAILING DATE of this communication appears on the c ver sheet with the c rrespondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 May 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-30* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-30* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *5,11,16* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

Detailed Action

The following is responsive to Applicant's remarks and declaration received May 6, 2003.

No claims are cancelled. No new claims are added. Claims 1-30 are currently pending.

The declaration under 37 CFR 1.132 filed May 6, 2003 is sufficient to overcome the rejection of claims 1-30 based upon 35 USC 103(a) over Barbachyn et al., 5,688,792 in view of Bartroli et al., 5,646,294. (please see paragraphs 2-4 of the office action mailed March 29, 2002). Therefore this rejection **is withdrawn**.

However, in view of the following new grounds of rejection below, the finality of the office action mailed Dec. 31, 2002 is withdrawn and prosecution on the merits is reopened.

New Ground(s) of Rejection

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 22-30 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The claims are drawn to a method of treating or preventing infective disease in a subject by administering an effective amount of the

composition set forth in claim 1 or the use of the composition of claim 1 in the manufacture of a medicament for treating or preventing infective disease. The claimed methods of treatment or prevention fail to meet the requirement for an adequate written description of the claimed invention as required by 35 USC, 112, paragraph 1.There is insufficient descriptive support for the generic limitation "infective disease", which may include diseases caused by agents ranging from bacteria to viruses to fungi to parasites. Furthermore, the claimed methods require treatment of an unspecified disease, and no evidence indicates that a treatable disease, other than those caused by gram-positive bacteria, anaerobic bacteria and acid-fast bacteria, was known to Applicant (please see the specification page 6). In the absence of some understanding of the diseases to be treated one of ordinary skill in the art would not have concluded that Applicant was in possession of the generically claimed method.

Claim Rejection -- 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.

4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Barbachyn et al., 5,688,792 (already of record) in view of Hillard (submitted by Applicant in IDS) and WO 0018387 (submitted by Applicant in IDS).

Barbachyn et al. disclose antimicrobial oxazolidinone derivatives such as linezolid, wherein said compounds are formulated into compositions for treating patients suffering microbial infections. Please see col. 1, lines 5-13; col. 2, lines 21-67. The compounds may be administered orally, parenterally (by injection, intravenous injection or infusion) or topically at a dose comprising 0.1 to about 100 mg/kg of body weight. Please see col. 3, lines 1-5; col. 7, lines 33-36. The oxazolidinone compounds are combined with a solid or liquid pharmaceutically acceptable carrier and, optionally, adjuvants or excipients employing standard and conventional techniques. The compounds may be dissolved in water, water-propylene glycol and water-polyethylene glycol systems along with conventional coloring agents, flavoring agents, stabilizers and thickening agents. Please see col. 6, lines 45-65. Finally, the compositions for parenteral administration (injection) contain the oxazolidinone compounds dissolved in water and a buffer to provide a suitably buffered isotonic solution with a pH of 3.5 to 7. When the oxazolidinone derivatives are dissolved in the injectable formulations, it will be present in the range of 1 mg/ml to about 400 mg/ml of solution. Please see col. 7, lines 32-53.

Barbachyn et al. do not disclose adding a cyclodextrin compound to the composition and methods; however, the Examiner refers to (1) the Hillard reference,

which studies the effect of cyclodextrins on three oxazolidinone compounds and ultimately discloses that cyclodextrins can be used to enhance the solubility of oxazolidinones (please see page 1 and 22); and (2) WO '387 which discloses that ophthalmic, otic and nasal compositions containing oxazolidinones may contain solubility enhancing agents such as cyclodextrins (please see the abstract; page 10, lines 21-25).

Therefore it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the methods and composition of Barbachyn et al. to include the cyclodextrins taught by Hillard and WO '387 because Hillard and WO '387 teach and therefore strongly suggests that cyclodextrins would enhance the solubility of the oxazolidinone compounds. Such a modification would have been motivated by the reasoned expectation of enhancing the solubility of the oxazolidinone compounds in the injectable pharmaceutical formulations of Barbachyn et al., thereby producing a pharmaceutical composition that will be effectively delivered to the patient undergoing treatment.

Concerning the claimed concentrations of cyclodextrin, since concentration of the cyclodextrin will affect the solubility of the oxazolidinone compounds, it would have been obvious to one of ordinary skill in the art to further modify the concentration of cyclodextrins such that they are present at a concentration which is effective to optimize their solubilizing effect on the oxazolidinone compounds.

In addressing claims 9, 11 and 29, modification of the compositions and methods of the prior art to contain other know antibacterial oxazolidinone compounds would have

been obvious and well within the capability of the skilled artisan. Finally, with respect to claim 15, absent evidence to the contrary, modification of the compositions and methods of the prior art to use known cyclodextrins such as sulfobutylether-beta-cyclodextrin would have been obvious and well within the capability of the skilled artisan.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cybille Delacroix-Muirheid whose telephone number is 703-306-3227. The examiner can normally be reached on Tue-Thur. from 8:30 to 6:00. The examiner can also be reached on alternate Mondays .

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marianne Seidel, can be reached on (703) 308-4725 The fax phone number for the organization where this application or proceeding is assigned is 703-308-7924.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

CDM

July 30, 2003

ZARNEY FAY
PRIMARY EXAMINER
GROUP 1200